Clinical trials in the country

1450. SHRI B.K. HARIPRASAD: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether according to reports from US National Institute of Health, the number of clinical trials by global pharma majors conducted in India has more than doubled in just one year;

(b) if so, whether a proper monitoring mechanism is in place in the country to ensure that global safety parameters on clinical trials are followed; and

(c) whether patients enrolling for clinical trials in the country are financially compensated beyond the benefits of free treatment and transportation?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) and (b) There is a moderate growth in Clinical trials of new drugs in India. As regulation for conducting Clinical Trials in the country are amended recently, *i.e.* Rules 122 DA-122 E and Schedule Y of Drugs and Cosmetics Rules which is amended in year 2005. Good Clinical Practices (GCP) Guidelines introduced by the Ministry in the year 2001 and Ethical Guidelines were issued by ICMR in the year 2000. This ensures proper monitoring mechanism and safety parameters to be followed.

(c) Clinical trials are being conducted as per rules and regulations and Good Clinical Practices (GCP) guidelines in the country.

Harassment of CGHS beneficiaries

1451. SHRI MOTIUR RAHMAN: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether CGHS beneficiaries in Delhi are being harassed in the matter of making available the indented medicines by the authorized chemists while the same is available at their shops, supplying tablets in place of syrups, etc., after 3-4 days of indenting the medicines;

(b) if so, how many cases have been reported to Government by the CGHS dispensaries during the last one year and the action taken thereon; and

(c) if the dispensaries have not brought the matter to the notice of Government whether Government propose to inquire into the matter of their own to ensure meaningful service to the beneficiaries?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) to (c) By and large the medicines are provided within the stipulated time except for occasional delay by the authorized chemists. There is a provision for imposition of fines in the tender document through which local chemists were empanelled for each dispensary. Action taken against the local authorize chemists who not fulfilling the conditions is enclosed as Statement (*See* below).

The formulary medicines if available in the dispensary with a different brand/ generic name, having the same chemical composition and similar therapeutic action,